Olin Brass

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VIA ELECTRONIC MAIL
Mark Perry, Team Leader,
Efficacy Evaluation
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
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Dear Mr. Perry:

On behalf of GBC Metals LLC dba Olin Brass, we hereby support the comments filed by the Copper Development Association regarding the proposed *Protocol for the Evaluation of Bactericidal Activity of Hard, Non-porous Copper/Copper-Alloy Surfaces* released for public comment on October 2, 2014.

Olin Brass is currently the largest U.S. supplier of EPA-registered solid copper alloy materials, registered under the *CuVerro* trademark. More than 20 affiliate companies—fully registered in all 50 states—have developed products that are being sold under the distinct brand name of CuVerro. Each has invested heavily to conform to EPA federal and state registration, labeling and promotional requirements. These U.S. manufacturing firms have invested substantially in alloy development, prototype builds, legal fees, branding, market development, and clinical testing based on EPA labeling requirements, and the proposed test protocols risk undermining these efforts.

Olin Brass is pleased to submit the following comments regarding this draft "*Protocol.*"

- Copper alloys represented by CuVerro materials have been evaluated by rigorous test methods developed and approved by the EPA to specifically assess the efficacy and durability of solid copper alloy products. The ***data supporting existing claims*** for solid copper alloys ***remains valid***, and any proposed ***new test protocols should be supplemental to or optional*** to current EPA label claims.
- Our understanding is that data call-ins (DCIs) are used to obtain information in *support of existing active product registrations* in order to complete a risk assessment; and that product reviews are used to insure that pesticide products can perform their intended function *without unreasonable adverse effects on human health or the environment.*

  We believe that solid copper alloys continue to provide the efficacy demonstrated in the original test protocols, and that the Agency has not indicated that there are any questions regarding:

  - The ability of solid copper alloys to kill the tested bacteria within two hours; nor the ability to demonstrate continual antibacterial activity after multiple re-inoculations.

- The ability of homogeneous (copper) alloy materials to provide continued efficacy when subjected to abrasives, cleaning chemicals and/or other usual wear over the expected life of the products for which they are used. (Note that the expected useful life of door hardware, for example, is greater than 50 years; and the integrity of a solid copper alloy has been proven to hold up over that time. And in healthcare settings clinical trials have shown these materials to remain effective under years of cleaning with standard hospital disinfectants.)
- Any adverse effects of solid copper alloys on human health or the environment.

The requirement of the proposed new protocol defies the "rational and creative approach" that is the EPAs goal as defined in the DCI document. We believe the existing protocol is satisfactory for the CuVerro alloy products and associated claims. Requiring existing registrants to comply with the new protocol is neither "timely" nor "cost effective". As previously indicated above, the costs to develop, launch and maintain products associated with existing EPA label claims has been extraordinary. Without evidence that current test protocols are not addressing the above, any new protocol should not preempt existing protocols.

- Olin Brass understands the EPA's interest in establishing a better understanding of non-homogenous solid surfaces, where antibacterial substances have been added to coatings or infused in polymeric substrates. We support EPA's effort to provide more aggressive chemical and physical wear testing of materials claiming antibacterial properties. These tests should:
  - Provide additional claims—and not displace current claims.
  - Be designed to test chemical and abrasive effects independently, and represent normal wear over the anticipated product life.
  - Follow protocols that are proven, reasonable and not cost prohibitive.
- A substantial amount of time and resources has been invested to develop, register and market solid copper alloys that *have conformed to tests that effectively represent* the ability of these materials to kill bacteria. Displacing current protocols will put this considerable investment—for Olin Brass and entire supply chain—at risk.
- A key public health benefit of CuVerro surfaces is their ability to provide continuous bactericidal properties between cleaning, and for the life of the product. Any future efficacy testing of products intended to protect public health should focus on evaluating the extent to which these products provide continuous reductions when faced with repeated bacterial challenges. The proposed protocol does not assess efficacy after repeated contamination typical of conditions representative of anticipated use. It is therefore paramount that the existing "continuous reduction" protocol remain the baseline for efficacy evaluation.
- Current EPA test protocols are based on a two-hour kill. Olin Brass feels that this appropriately represents EPA's intent that solid bactericidal surfaces do not suggest a 'quick fix.' Nor does such a kill time in any way influence an institution to moderate standard cleaning protocols. Current registration and practice support this objective.

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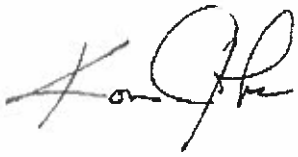
We are concerned that an arbitrary reduction in the kill time claim could have a negative impact on the general understanding that solid surfaces must be used as a supplement to, and not be a substitute for standard infection control practices.

- The proposed new protocol does not cover the range of bacteria covered in the original protocol. These represent pathogens that significantly impact hospital-acquired and community-acquired infections, and elimination of these organisms from the test protocol diminishes concerns relative to threats to public health.
- Olin Brass is concerned that the recommended test procedures for the new protocol are not standard, have not been tested, and will potentially put an undue financial burden on registrants. One laboratory estimates that one test might cost $150,000 to conduct. This supports the above comment that any new testing be supplemental to existing label claims. The EPA needs to consider the economic impact on the U.S. manufacturers that have entered and are entering the market with these products.
- To date, installations of solid copper alloys have been completed in many facilities—the majority healthcare related, but also including hospitality, education, fitness, and public spaces. These facilities have spent thousands of dollars to specifically use the existing product registration label claims in promoting their businesses. Without retaining current test protocols as a baseline, Olin Brass is concerned about the ability of these facilities to promote the existing claims. Marketplace and consumer confusion can be expected, which further hampers efforts of dozens of manufacturers to maintain and further build their antimicrobial business model.

Olin Brass appreciates EPA's efforts to establish consistent test protocols for all solid surfaces claiming continuous and long-lasting bactericidal properties. We appreciate the opportunity to submit these comments and stand willing to provide further support in EPA's efforts.

Best regards,



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